IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of LI *et al.*

Group Art Unit: 1616

Application Serial No.: TBD

Examiner: Hartley, M.

Filed: July 14, 2003

Docket No.: 1401S

For: WATER SOLUBLE PACLITAXEL DERIVATIVES

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

DEPOSIT ACCOUNT USE AUTHORIZATION
Charge any fee due to our DEPOSIT ACCOUNT NO. 03-1182.

The attention of the Patent and Trademark Office is hereby directed to the reference(s) listed on the attached Form SB-08. The references have been submitted to the Examiner in the parent application and are not attached herewith. Additional copies of references are available on request. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

☒ 1. This Information Disclosure Statement is being filed within three months of the U.S. filing date OR before the mailing date of a first Office Action on the merits. No certification or fee is required. 37 CFR 1.97(b)(1)(2)(3).

☐ 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection or Notice of Allowance. 37 CFR 1.97(c)(1)(2).

☐ a. I hereby certify that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(1).

☐ b. I hereby certify that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable

inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(2).

☐ c. Please debit or credit the $240.00 fee to Account No. 03-1182 under 37 C.F.R. 1.17(p), or as needed to ensure consideration of the disclosed information. A duplicate copy of this paper is attached.

☐ 3. This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but before payment of the Issue Fee. A petition requesting reconsideration of the Information Disclosure Statement along with the requisite fee set forth under 37 CFR 1.17(i) accompanies this Information Disclosure Statement. Please debit or credit the $130.00 fee to Account No. 03-1182, or as needed to ensure consideration of the disclosed information. A duplicate copy of this paper is attached. 37 CFR 1.97(d)(1)(2)(3).

☐ a. I hereby certify that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(1).

☐ b. I hereby certify that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(2).

Applicants respectfully request that the listed documents be considered by the Examiner and formally be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609. The references listed in the attached SB-08 have been submitted in the parent application. Additional copies are available on request.

The Information Disclosure Statement filed in accordance with this section shall not be construed as a representation that a search has been made. The filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR 1.56(b).

Respectfully submitted,

Date: July 14, 2003

By: _____
Donald W. Wyatt, Reg. No. 40,879
Attorney for Applicants

CELL THERAPEUTICS, INC.
501 Elliott Avenue West, Suite 400
Seattle, Washington 98119
Telephone No.: (206) 272-4243
Facsimile No.: (206) 272-4397

PTO/SB/08 (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act f 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO				Complete If Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	July 14, 2003
Date Submitted: March 22, 2002				First Named Invent r	LI
				Group Art Unit	1616
(use as many sheets as necessary)				Examiner Name	Hartley
Sheet	1	of	11	Attorney Docket Number	1401S

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	U.S. Patent Document Number	U.S. Patent Document Kind Code[2] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A1	2001/0034363	A1	Li et al.	10/25/2001	
	A2	2002/0016285	A1	Bhatt et al.	02/07/2001	
	A3	4,356,166		Peterson et al.	10/26/1982	
	A4	4,942,184		Haugwitz et al.	07/17/1990	
	A5	4,943,579		Vishnuvajjala et al.	07/24/1990	
	A6	4,960,790		Stella et al.	10/02/1990	
	A7	5,059,699		Kingston et al.	10/22/1991	
	A8	5,087,616		Myers et al.	02/11/1992	
	A9	5,169,933		Anderson et al.	12/08/1992	
	A10	5,219,564		Zalipsky et al.	06/15/1993	
	A11	5,340,817		Wall et al.	08/23/1994	
	A12	5,362,831		Mongelli	11/08/1994	
	A13	5,380,751		Chen et al.	01/10/1995	
	A14	5,422,364		Nicolaou et al.	06/06/1995	
	A15	5,468,769		Klein et al.	11/21/1995	
	A16	5,473,055		Mongelli et al.	12/05/1995	
	A17	5,489,525		Pastan	02/06/1996	
	A18	5,545,880		Bu et al.	08/13/1996	
	A19	5,569,720		Mongelli et al.	10/29/1996	
	A20	5,583,153		Brahn	12/10/1996	
	A21	5,607,659		Gustavson et al.	03/04/1997	
	A22	5,614,549		Greenwald et al.	03/04/1997	
	A23	5,621,001		Canetta et al.	04/15/1997	
	A24	5,626,862		Brem et al.	05/06/1997	
	A25	5,629,433		Zheng et al.	05/13/1997	
	A26	5,641,803		Carretta et al.	06/24/1997	
	A27	5,646,159		Wall et al.	07/08/1997	
	A28	5,648,506		Desai et al.	07/15/1997	
	A29	5,716,981		Hunter et al.	02/10/1998	
	A30	5,719,265		Mongelli et al.	02/17/1998	
	A31	5,730,968		Butterfield et al.	03/24/1998	
	A32	5,733,925		Kunz et al.	03/31/1998	
	A33	5,762,909		Uzgiris	06/09/1998	
	A34	5,773,522		Angelucci et al.	06/30/1998	
	A35	5,776,925		Young et al.	07/07/1998	
	A36	5,783,178		Kabanov et al.	07/21/1998	
	A37	5,811,447		Kunz et al.	09/22/1998	
	A38	5,837,673		Tsujihara et al.	11/17/1998	
	A39	5,846,565		Brem et al.	12/08/1998	
	A40	5,854,006		Hanigan et al.	12/29/1998	
	A41	5,873,904		Ragheb et al.	02/23/1999	
	A42	5,880,131		Greenwald et al.	03/09/1999	
	A43	5,886,026		Hunter et al.	03/23/1999	

Examiner Signature		Dat Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number. [2]See attached Kinds of U.S. Patent Documents. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08 (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, n persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO				Complete if Kn wn	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	July 14, 2003
Date Submitted: March 22, 2002				First Named Inventor	LI
				Group Art Unit	1616
(use as many sheets as necessary)				Examiner Name	Hartley
Sheet	2	of	11	Attorney Docket Number	1401S

U.S. PATENT DOCUMENTS

		U.S. Patent Document				
	A44	5,892,043		Tsujihara et al.	04/06/1999	
	A45	5,916,896		Wall et al.	06/29/1999	
	A46	5,977,163		Li et al.	11/02/1999	
	A47	5,981,568		Kunz et al.	11/09/1999	
	A48	6,005,020		Loomis	12/21/1999	
	A49	6,011,042		Greenwald et al.	01/04/2000	
	A50	6,028,164		Loomis	02/22/2000	
	A51	6,127,355		Greenwald et al.	10/03/2000	
	A52	6,218,367	B1	Jacob	04/17/2001	
	A53	6,262,107	B1	Li et al.	07/17/2001	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Office[3]	Number[4]	Kind Code[5] (if known)	Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	A54	WO	93/10121	A1	Hans (w/Abstract)	05/27/1993		
	A55	JP	5286868	A	Kiyoshi et al. (w/Abstract)	11/02/1993		
	A56	WO	95/03036	A1	Hunter et al.	02/02/1995		
	A57	WO	95/13053	A1	Straubinger et al.	05/18/1995		
	A58	EP	0589281	B1	Gasteier (w/Abstract) **	03/13/1996		
	A59	WO	96/25176	A1	Kunz et al.	08/22/1996		
	A60	EP	0558959	B1	Uedal et al.	04/16/1997		
	A61	WO	97/33552	A1	Li et al.	09/18/1997		
	A62	WO	99/17804	A1	Angelucci et al.	04/15/1999		
	A63	WO	99/49901	A1	Li et al.	10/07/1999		
	A64	EP	0604910	B1	Golik et al.	06/14/2000		
	A65	WO	01/70275	A2	Bhatt et al.	09/27/2001		

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of th item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[6]
	A66	BALOG ET AL., "Total Synthesis of (-) Epothilone A," *Angew. Chem. Int. Ed. Engl.*, Vol. 35, 1996, pp. 2801-2803 © VCH Verlagsgesellschaft mbH, Weinheim	
	A67	BARTOLI ET AL., "*In Vitro* and *In Vivo* Antitumoral Activity of Free, and Encapsulated Taxol," *J. Microencapsulation*, Vol. 7, 1990, pp. 191-197 © Taylor & Francis Ltd.	
	A68	BOM ET AL., "The Novel Silatecan 7-*tert*-Butyldimethylsilyl-10-hydroxycamptothecin Displays High Lipophilicity, Improved Human Blood Stability, and Potent Anticancer Activity," *Journal of Medicinal Chemistry*, Vol. 43, No. 21, 2000, pp. 3970-3980, © American Chemical Society	
	A69	BORMAN, S., "Epothilone Epiphany: Total Syntheses," *C&EN*, Vol. 74, 1996, pp. 24-26 © American Chemical Society	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number. [2]See attached Kinds of U.S. Patent Documents. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08 (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	July 14, 2003
Date Submitted: March 22, 2002				First Named Inv nt r	LI
				Group Art Unit	1616
(use as many sheets as necessary)				Examiner Name	Hartley
Sheet	3	of	11	Attorney Docket Number	1401S

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[6]
	A70	CAIOLFA ET AL., "Polymer-bound camptothecin: initial biodistribution and antitumor activity studies," *Journal of Controlled Release*, Vol. 65, 2000, pp. 105-119, © Elsevier Science B.V.	
	A71	CONOVER ET AL., "Camptothecin delivery systems: enhanced efficacy and tumor accumulation of camptothecin following its conjugation to polyethylene glycol via a glycine linker," *Cancer Chemother Pharmacol*, Vol. 42, 1998, pp. 407-414, © Springer-Verlag	
	A72	CONOVER ET AL., "Camptothecin Delivery Systems: The Utility of Amino Acid Spacers for the Conjugation of Camptothecin with Polyethylene Glycol to Create Prodrugs," *Anti-Cancer Drug Design*, Vol. 14, 1999, pp. 499-506, © Oxford University Press	
	A73	CONOVER ET AL., "Camptothecin Delivery Systems: The Antitumor Activity of a Camptothecin-20-0-Polyethylene Glycol Ester Transport Form," *Anticancer Research*, Vol. 17, 1997, pp. 3361-3368	
	A74	CORTES ET AL., "Docetaxel," *J. of Clinical Oncolgy*, Vol. 13, 1995, pp. 2643-2655 © American Society of Clinical Oncology	
	A75	DE BONO ET AL., "Phase I Pharmacokinetic (PK) Study of Mag-CPT-(PNO 166148) A Polymer Derivative of Camptothecin (CPT)," *Pharmicia*	
	A76	DE VRIES ET AL., "Conjugation of Docetaxel (DTXL) to Poly L-Glutamic Acid (PG) Increases Anti-Tumor Efficacy," *Proceedings of the American Association for Cancer Research*, Vol. 41, 2000, pg. 323, Abstract No. 2051	
	A77	DE VRIES ET AL., "CT-2103: A water soluble poly-L-glutamic acid (PG)-Paclitaxesl (TXL) conjugate has enhanced efficacy on MDR-1+human colon carcinoma cell line xenografts compared to free TXL," *AACR*, 2001, Abstract No. 462	
	A78	DE VRIES ET AL., "Optimization of the anti-tumor activity of water-soluble poly L-glutamic acid (PG)-paclitaxel (TXL) conjugates," *AACR-NCI-EORTC 92*, 1999, p. 22, Abstract No. 451, Washington, DC	
	A79	DE VRIES ET AL., "Pharmacokinetcis (PK) and biodistribution of poly-(L)-glutamic acid (PG) paclitaxesl (TXL) (CT-2103) in mice with subcutaneous B-16 melanomas," *Proceedings of the 11th AACR-NCI-EORTC Symposium*, 2000 Amsterdam, Netherlands	
	A80	DEUTSCH ET AL., "Synthesis of Congeners of Prodrugs. 3. Water-Soluble Prodrugs of Taxol with Potent Antitumor Activity," *J. Med. Chem.*, Vol. 32, 1989, pp. 788-792 © American Chemical Society	
	A81	DUNCAN ET AL., "Polymer-drug conjugates, PDEPT and PELT: basic principles for design and transfer from the Laboratory to Clinic," *Journal of Controlled Release*, Vol. 74, 2001, pp. 135-146, © Elsevier Science B.V.	
	A82	EISEMAN ET AL., "Plasma pharmcokinetics and tissue distribution of paclitaxel in CD2F1 mice," *Cancer Chemother. Pharmacol.*, Vol. 34, 1994, pp. 465-471 © Springer-Verlag	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number. [2]See attached Kinds of U.S. Patent Documents. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08 (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	July 14, 2003
Date Submitted: March 22, 2002				First Named Inventor	LI
				Group Art Unit	1616
(use as many sheets as necessary)				Examiner Name	Hartley
Sheet	4	of	11	Attorney Docket Number	1401S

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[6]
	A83	FIDLER ET AL., "The Biology of Cancer Invasion and Metastasis," *Adv. Cancer Res.*, Vol. 28, 1978, pp. 149-250 © Academic Press, Inc.	
	A84	GILBERT ET AL., "Novel water soluble paclitaxel derivatives: Evaluation of PEG-paclitaxel's *in vitro* and *in vivo* effects," *Proc. Amer. Assoc. Cancer Res.*, Vol. 38, 1997, pg. 225, Abstract #1512	
	A85	GOLDSPIEL, "Pharmaceutical Issues: Preparation, Administration, Stability, and Compatibility with Other Medications," *Ann. Pharmacotherapy*, Vol. 28, 1994, pp. S23-26, © Harvey Whitney Books Company	
	A86	GREENWALD ET AL., "Camptothecin-20-PEG Ester Transport Forms: the Effect of Spacer Groups on Antitumor Activity," *Bioorganic & Medicinal Chemistry*, Vol. 6, 1998, pp. 551-562, © Elsevier Science Ltd.	
	A87	GREENWALD ET AL., "Drug Delivery Systems. 2. Camptothecin 20-*O*-Poly(ethylene glycol) Ester Transport Forms," *J. Med. Chem.*, Vol. 39, 1996, pp. 1938-1940, © American Chemical Society	
	A88	GREENWALD ET AL., "Drug Delivery Systems: Water Soluble Taxol 2'-Poly(Ethylene Glycol) Ester Prodrugs-Design and *In Vivo* Effectiveness," *J. Med Chem.*, Vol. 39, 1996, pp. 424.431 © American Chemical Society	
	A89	GREENWALD ET AL., "Highly Water Soluble Taxol Derivatives: 2'-Polyethylene Glycol Esters as Potential Products," *J. Org. Chem.*, Vol. 60, 1995, pp. 331-336 © American Chemical Society	
	A90	GREENWALD ET AL., "Highly Water Soluble Taxol Derivatives: 2'-polyethyleneglycol esters as potential prodrugs," *Bioorganic & Medicinal Chemistry Letters*, Vol. 4, 1994, pp. 2465-2470 © Elsevier Science Ltd.	
	A91	GREENWALD ET AL., "Stereoselective acylation of 20-(*S*)-camptothecin with amino acid derivatives using scandium triflate/DMAP," *Tetrahedron: Asymmetry*, Vol. 9, 1998, pp. 915-918, © Elsevier Science Ltd.	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number. [2]See attached Kinds of U.S. Patent Documents. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08 (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				**Applicati n Number**	
				Filing Date	July 14, 2003
Date Submitted: March 22, 2002				**First Named Inventor**	LT
				Group Art Unit	1616
(use as many sheets as necessary)				**Examiner Name**	Hartley
Sheet	5	of	11	**Attorney Docket Number**	1401S

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[6]
	A92	GREENWALD, "Camptothecin-20-PEG Ester Transport Forms: the Effect of Spacer Groups on Antitumor Activity", *Bioorganic & Medicinal Chemistry*, Vol. 6, 1998, pp. 551-562 © Elsevier Science Ltd.	
	A93	HIRANO ET AL., "Polymeric derivatives of activated cyclophosphamide as drug delivery systems in antitumor therapy pharmacologically active polymers, 20," *Makromol. Chem.*, Vol. 180, 1979, pp. 1125-1130 © Hüthig & Wepf Verlag, Basel, Heidelberg	
	A94	HOES ET AL., "Optimization of macromolecular prodrugs of the antitumor antibiotic adriamycin," *J. Controlled Release*, Vol. 2, 1985, pp. 205-213 © Elsevier Science Publishers B.V.	
	A95	HÖFLE ET AL., "Epothilone A and B – novel 16-membered macrolides with cytotoxic activity: isolation, crystal structure, and conformation in solution," *Angew. Chem. Int. Ed. Engl.*, Vol. 35, 1996, pp. 1567-1569 © VCH Verlagsgesellschaft mbH	
	A96	HORWITZ ET AL., "Taxol, mechanisms of action and resistance," *J. Natl. Cancer Inst. Monographs*, Vol. 15, 1993, pp. 55-61	
	A97	KATO ET AL., "Antitumor activity of 1-β-D-arabinofuranosylcytosine conjugated with polyglutamic acid and its derivative," *Cancer Res.*, Vol. 44, 1984, pp. 25-30	
	A98	KE ET AL., "Elevated serum VEGF as a prognosis marker in combined radiation and PG-TXL (CT-2103) therapy in mice with murine ovarian OCa-1 tumor," *Proc Amer Assoc Cancer Res*, Vol. 42, 2001, Abstract No. 3873	
	A99	KE ET AL., "Schedule-independent radiosensitization of a murine ovarian OCa-1 tumor by PG-TXL," *Proc Am Assoc Cancer Res*, Vol. 40, 1999, Abstract No. 4223	
	A100	KE ET AL., "Potentiation of radioresponse by polymer-drug conjugates," *J.Control Release*, Vol. 74, 2001, pp. 237-242 © Elsevier Science B.V.	

Examin r Signature		Dat Consid red	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number. [2]See attached Kinds of U.S. Patent Documents. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08 (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under th Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO				Complete if Kn wn	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Applicati n Number	
				Filing Date	July 14, 2003
Date Submitted: March 22, 2002				First Named Inventor	LI
				Group Art Unit	1616
(use as many sheets as necessary)				Examiner Name	Hartley
Sheet	6	of	11	Attorney Docket Number	1401S

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[6]
	A101	KOPEČEK, "The potential of water-soluble polymeric carriers in targeted and site-specific drug delivery," *J. Controlled Release*, Vol. 11, 1990, pp. 279-290 © Elsevier Science Publishers B.V.	
	A102	KOUSKOFF ET AL., "Organ-specific disease provoked by systemic autoimmunity," *Cell*, Vol. 87, 1996, pp. 811-822 © Cell Press	
	A103	KUANG ET AL., "Poly(benzyl-l-glutamate) microcapsules: Their diagnostic and therapeutic potential," *Pharm. Res.*, Vol. 10, 1993, pg. S-191, Abstract PDD 7066 © Plenum Press	
	A104	LI ET AL., "Complete Regression of Well-Established Tumors Using a Novel Water-Soluble Poly-(L-Glutamic Acid)-Paclitaxel Conjugate," *Cancer Research*, Vol. 58, 1998, pp. 2404-2409	
	A105	LI ET AL., "Synthesis and evaluation of PEG-paclitaxel conjugate as a water-soluble paclitaxel prodrug," *Proc. Amer. Assoc. Cancer Res*, Vol. 37, 1996, p. 376, Abstract No. 2569	
	A106	LI ET AL., "Cytotoxic and antitumor activity of water-soluble paclitaxel prodrug," *Proc. Amer. Assoc. Cancer Res*, Vol. 37, 1996, pp. 376-377, Abstract No. 2570	
	A107	LI ET AL., "Formation and characterization of CDDP loaded poly(benzyl L-glutamate) and poly (dl-lactic acid) microcarpsules for chemoembolization," *Proc. Amer. Assoc. Cancer Res.*, Vol. 35, 1994, p. 336, Abstract No. 2003	
	A108	LI ET AL., "Synthesis, biodistribution and imaging properties of indium-111-DTPA-paclitaxel in mice bearing mammary tumors," *J. Nucl. Med.*, Vol. 38, 1997, pp. 1042-1047	
	A109	LI ET AL., "Water-soluble polyglutamic acid paclitaxel conjugate (PGA-paclitaxel): antitumor regression in rats braeing 13762 mammary carcinoma," *American Association Pharmaceutical Scientists Meeting*, Vol. 13, 1996, p. S368	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number. [2]See attached Kinds of U.S. Patent Documents. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08 (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449B/PTO				Complete If Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Applicati n Number	
				Filing Date	July 14, 2003
Date Submitted: March 22, 2002				First Named Inventor	LI
				Group Art Unit	1616
(use as many sheets as necessary)				Examiner Name	Harley
Sheet	7	of	11	Attorney Docket Number	1401S

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[6]
	A110	LI ET AL., "Synthesis and evaluation of water-soluble polyethylene glycol-paclitaxel conjugate as a paclitaxel prodrug," *Anticancer Drugs*, Vol. 7, 1996, pp. 642-618	
	A111	LI ET AL., "Complete regression of well-established tumors using a novel water-soluble poly(L-glutamic acid)-paclitaxel conjugate," *Cancer Res*, Vol. 58, 1998, pp. 2404-2409	
	A112	LI ET AL., "Antitumor activity of Poly(L-glutamic acid)-Paclitaxel on syngeneic and xenografted tumors," *Proc Am Assoc Cancer Res*, Vol. 40, 1999, Abstract No. 1909	
	A113	LI ET AL., "Enhancement of tumor radioresponse of a murine ovarian carcinoma by poly(L-glutamic acid)-paclitaxel conjugate," *Ninth International Symposium on Recent Advances in Drug Delivery Systems*, 1999, Salt Lake City, UT	
	A114	LI ET AL., "Antitumor activity of Poly(L-glutamic acid)-Paclitaxel on syngeneic and xenografted tumors," *Clin Cancer Res*, Vol. 5, 1999, pp. 891-897	
	A115	LI ET AL., "Tumor irradiation enhances the tumor-specific distribution of poly(L-glutamic acid)-conjugated paclitaxel and its antitumor efficacy," *Clin Cancer Res*, Vol. 6, 2000, pp. 2829-2834	
	A116	LI ET AL., "Biodistribution of paclitaxel and poly(L-glutamic acid)-paclitaxel conjugate in mice with ovarian OCa-1 tumor," *Cancer Chemother Pharmacol*, Vol. 46, 2000, pp. 416-422 © Springer-Verlag	
	A117	LI ET AL., "Potentiation of ovarian OCa-1 tumor radioresponse by poly (L-glutamic acid)-paclitaxel conjugate," *Int.J Radiat. Oncol. Biol. Phys.*, Vol. 48, 2000, pp. 1119-1126 © Elsevier Science Inc.	
	A118	MAEDA ET AL., "Tumoritropic and lymphotropic principles of macromolecular drugs," *Critical Reviews in Therapeutic Drug Carrier Systems*, Vol. 6, 1989, pp. 193-210 © CRC Press	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number. [2]See attached Kinds of U.S. Patent Documents. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08 (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	July 14, 2003
Date Submitted: March 22, 2002				First Named Inventor	LI
				Group Art Unit	1616
(use as many sheets as necessary)				Examiner Name	Hartley
Sheet	8	of	11	Attorney Docket Number	1401S

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[6]
	A119	MAGRI ET AL., "Modified Taxols. 2. Oxidation Products of Taxol," *J. Org. Chem.*, Vol. 51, 1986, pp. 797-802 © American Chemical Society	
	A120	MATHEW ET AL., "Synthesis and evaluation of some water-soluble prodrugs and derivatives of taxol with antitumor activity," *J. Med. Chem.*, Vol. 35, 1992, pp. 145-151 © American Chemical Society	
	A121	MASON ET AL., "Poly (L-glutamic Acid)-paclitaxel dramatically enhances the anti-tumor efficacy of radiotherapy," *AACR - NCI - EORTC*, Vol. 397, 2001, Miami Beach, Florida	
	A122	MULTANI ET AL., "Paclitaxel and water-soluble poly (L-gluatmic acid)-paclitaxel, induce direct chromosomal Abnormalities and cell death in a murine metastatic melanoma cell line," *Anticancer Res*, Vol. 17, 1997, pp. 4269-4274	
	A123	MORIMOTO ET AL., "Antitumor agent poly (amino acid) conjugates as a drug carrier in cancer chemotherapy," *J. Pharm. Dyn.*, Vol. 7, 1984, pp. 688-698	
	A124	MOSMANN, "Rapid colorimetric assay for cellular growth and survival: application to proliferation and cytotoxic assay," *J. Immunol. Methods*, Vol. 65, 1983, pp. 55-63 © Elsevier Science Publishers B.V.	
	A125	OLIVER ET AL., "Suppression of collagen-induced arthritis using an angiogenesis inhibitor, AGM-1470, and a microtubule stabilizer, Taxol," *Cellular Immunology*, Vol. 157, 1994, pp. 291-299 © Academic Press, Inc.	
	A126	PESENTI ET AL., "Synthesis and biological activity of water soluble polymer-bound taxol derivatives," *Proc. Amer. Assoc. Cancer Res.*, Vol. 36, 1995, p. 307, Abstract No. 1824.	
	A127	PHILLIPS-HUGHES ET AL., "Restenosis: pathophysiology and preventive strategies," *JVIR*, Vol. 7, 1996, pp. 321-333 © SCVIR	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number. [2]See attached Kinds of U.S. Patent Documents. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08 (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO				Complete If Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	July 14, 2003
Date Submitted: March 22, 2002				First Named Inventor	LI
				Group Art Unit	1616
(use as many sheets as necessary)				Examiner Name	Hartley
Sheet	9	of	11	Attorney Docket Number	1401S

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[6]
	A128	PRATESI ET AL., "Poly-L-Aspartic Acid as a Carrier for Doxorubicin: A Comparative *in vivo* Study of Free and Polymer-Bound Drug," *Br. J. Cancer*, Vol. 52, 1985, pp. 841-848 © The Macmillan Press Ltd.	
	A129	REYNOLDS ET AL., "Polymers help guide cancer drugs to tumor targets- and keep them there," *J. Natl. Cancer Institute*, Vol. 87, 1995, pp. 1582-1584	
	A130	ROSE ET AL., "Preclinical antitumor activity of water-soluble paclitaxel derivatives," *Cancer Chemother. Pharmacol.*, Vol. 39, 1997, pp. 486-492 © Springer Verlag	
	A131	SCUDIERO ET AL., "Evaluation of a soluble tetrazolium/formazan assay for cell growth and drug sensitivity in culture using human and other tumor cell lines," *Cancer Research*, Vol. 48, 1988, pp. 4827-4833	
	A132	SERRUYS ET AL., "A comparison of balloon-expandable-stent implantation with balloon angioplasty in patients with coronary artery disease," *N. Engl. J. Med.*, Vol. 331, 1994, pp. 489-495 © The Massachusetts Medical Society	
	A133	SHAFFER ET AL., "*In vivo* identification of monoglutamyl paclitaxel metabolite from poly-L-glutamic acid-paclitaxel (CT-2103) in tumor bearing mice," *Proceedings of the 49th ASMA Conference on Mass Spectrometry and Allied Topics*, A010970, 2001	
	A134	SHARMA ET AL., "Novel taxol formulations: preparation and characterization of taxol-containing liposomes," *Pharm. Res.*, Vol. 11, 1994, pp. 889-896 © Plenum Publishing Corp.	
	A135	SHI, "Poly (L-glutamic acid)-paclitaxel and paclitaxel have different pharmacological properties," *Proc. Amer. Assoc. for Cancer Research*, Vol. 39, 1998, p. 189, Abstract No. 1294	
	A136	SINGER ET AL., "Poly-L-Glutamic Acid Paclitaxel Conjugate (PG-TXL): A water-soluble biodegradable conjugate with decreased toxicity and enhanced efficacy," *4th International Symposium on Polymer Therapeutics*, 2000	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number. [2]See attached Kinds of U.S. Patent Documents. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08 (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	July 14, 2003
Date Submitted: March 22, 2002				First Named Inventor	LI
				Group Art Unit	1616
(use as many sheets as necessary)				Examiner Name	Hartley
Sheet	10	of	11	Attorney Docket Number	1401S

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[6]
	A137	SINGER ET AL., "Conjugation of Camptothecins to Poly-(L-Glutamic Acid)," *Annals of the New York Academy of Sciences*, Vol. 922, 2000, pp. 135-150, © The New York Academy of Sciences	
	A138	TODD ET AL., "Phase I and pharmacological Study of CT-2103, a poly (L-glutamic Acid)-paclitaxel conjugate," *Journal of Clinical Oncology*, Vol. 439, 2001.	
	A139	VAN HEESWIJK ET AL., "The Synthesis and Characterization of Polypeptide-Adriamycin Conjugates and its Complexes with Adriamycin. Part 1, *Journal of Controlled Release*, Vol. 1, 1985, pp. 301-315 Elsevier Science Publishers B.V.	
	A140	VYAS ET AL., "Phosphate-activated prodrugs of paclitaxel," *Taxane Anticancer Agents*, Chapter 9, 1995, pp. 124-137 © American Chemical Society	
	A141	WADKINS ET AL., " Water Soluble 20(*S*)-Glycinate Esters of 10,11-Methylenedioxycamptothecins Are Highly Active Against Human Breast Cancer Xenografts' *Cancer Research*, Vol. 59, 1999, pp. 3424-3428	
	A142	WALL ET AL., "Plant Antitumor Agents. 30.[18,b] Synthesis and Structure Activity of Novel Camptothecin Analogs," *Journal of Medicinal Chemistry*, Vol. 36, 1993, pp. 2689-2700, © American Chemical Society	
	A143	WANG ET AL., "Recent Advances in the Discovery and Development of Topoisomerase Inhibitors as Antitumor Agents," *Medicinal Research Reviews*, Vol. 17, 1997, pp. 367-425, © John Wiley & Sons, Inc.	
	A144	WEISS ET AL., "Hypersensitivity reactions from taxol," *J. Clin. Oncol.*, Vol. 8, 1990, pp. 1263-1268 © American Society of Clinical Oncology	
	A145	WEN ET AL., "Potentiation of Antitumor Activity of PG-TXL with Anti-EGFR Monoclonal Antibody C225 in MDA-MB-468 Human Breast Cancer Xenograft," *Proc Am Assoc Cancer Res*, Vol. 41, 2000, Abstract No. 2052	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number. [2]See attached Kinds of U.S. Patent Documents. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08 (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
				Filing Date	July 14, 2003
Date Submitted: March 22, 2002				First Named Inventor	LI
				Group Art Unit	1616
(use as many sheets as necessary)				Examiner Name	Hartley
Sheet	11	of	11	Attorney Docket Number	1401S

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[6]
	A146	YANG ET AL., "Application of surface-modified microcapsules to target estrogen receptors," *Pharm. Res.*, Vol. 9, 1992, p. S73, Abstract No. Biotec 2027	
	A147	YANG ET AL., "Diagnostic and therapeutic potential of poly(benzyl L-glutamate)," *J. Pharm. Sci*, Vol. 83, 1994, pp. 328-331 © American Chemical Society and American Pharmaceutical Association	
	A148	YU, "Effect of polymer structure on antitumor activity of polyaminio acid-paclitaxel conjugates," *Proc. Amer. Assoc. Cancer Research*, Vol. 39, 1998, p. 167, Abstract No. 1144	
	A149	ZHANG ET AL., "An investigation of the antitumor activity and biodistribution of polymeric micellar paclitaxel," *Cancer Chemother. Pharmacol*, Vol. 40, 1997, pp. 80-86 © Springer-Verlag	
	A150	ZHAO ET AL., "Modified taxols. 6. preparation of water-soluble taxol phosphates," *J. Nat. Prod.*, Vol. 54, 1991, pp. 1607-1611	
	A151	ZHENG ET AL., "Deacetylation of Paclitaxel and Other Taxanes," *Tetrahedron Letters*, Vol. 36, 1995, pp. 2001-2004, © Elsevier Science Ltd.	
	A152	ZUNINO ET AL., "Anti-Tumor Activity of Daunorubicin Linked to Poly-L-Aspartic Acid," *Int. J. Cancer*, Vol. 30, 1982, pp. 465-470	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number. [2]See attached Kinds of U.S. Patent Documents. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on